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| **Form** | | |
| **Recognition of orphan drug status** | | |
| **Identification number:** | ZL102\_00\_004 |
| **Version:** | 1.5 |
| **Valid from:** | 29.06.2023 |

# Basic information

|  |
| --- |
| **Name of medicinal product:** **……** |
| **Authorisation no.:** **……** |
| **Active substance(s):** **……** |
| **Pharmaceutical form**: **……** |
| **Dosage strength(s): ……** |
| **ATC code:** **……** |
| **IT No.:** **……** |
| **Orphan disease:** **……**  *If the application for recognition of the orphan drug status is based on the decision of a foreign authority, the wording of the "Orphan Designation" approved by the foreign authority should be stated in an official Swiss language.* |

# Addresses

## Marketing authorisation holder

|  |  |
| --- | --- |
| Company name: | …… |
| Addition: | …… |
| Street / no.: | …… |
| Postcode, town/city: | …… |
| Canton: | …… |
| Telephone: | …… |
| E-mail | …… |

## Address for correspondence (if not the same as 2.1)

|  |  |
| --- | --- |
| Company name: | …… |
| Addition: | …… |
| Street / no.: | …… |
| P.O. Box: | …… |
| Postcode, town/city: | …… |
| Telephone: | …… |
| E-mail | …… |

## Legal representative (if not the same as 2.1)

|  |  |
| --- | --- |
| Name: | …… |
| Addition: | …… |
| Street / no.: | …… |
| P.O. Box: | …… |
| Postcode, town/city: | …… |
| Telephone: | …… |
| **Does Swissmedic already possess the power of attorney?**  yes  no, the power of attorney is enclosed with this application (incl. original signature) | |

# Further information

## Proposed procedure

|  |  |
| --- | --- |
| The orphan drug status is requested on the basis of | |
|  | Art. 4 para. 1 letter adecies no. 1 TPA (independent review by Swissmedic) |
|  | Art. 4 para. 1 letter adecies no. 2 TPA (based on recognition of orphan drug status abroad)  Reference country: …… |

## Timing of submission of the authorisation application

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| --- | --- |
|  | At the same time as this application for recognition of the orphan drug status |
|  | Later, expected on …… |
|  | Timing not yet known |
|  | Authorisation application already submitted – application ID: |

## Orphan drug status abroad

The authorisation holder must inform Swissmedic of all decisions concerning the granting of orphan drug status issued by other countries having equivalent medicinal product control, in accordance with article 13 TPO (Art. 5 para. 2 TPLO). The list of countries can be found in the *List of all countries having comparable medicinal product control* on the Swissmedic website.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Status granted | Country: …… | Date of recognition of status: ……  Date of authorisation of medicinal product: ……  ☐ *The copies of the decisions of the foreign authorities are enclosed (compulsory according to Art. 4 para. 1 letter adecies no. 2 TPA).* | Name of the medicinal product: …… |
|  | Status withdrawn | Country: …… | Date of withdrawal: …… | Name of the medicinal product: …… |
|  | Status rejected | Country: …… | Date of rejection: …… | Name of the medicinal product: …… |
|  | Status requested | Country: …… | Date of application: …… | Name of the medicinal product: …… |

# Additional forms and documents to be submitted

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| --- |
| Is the Full declaration HMV4 form attached?  yes  no, the composition of the medicinal product is not yet known.  no, the form *Full declaration HMV4* was submitted to Swissmedic earlier on and is not altered by the present application. |
| Does the medicinal product contain genetically-modified organisms (GMO) per se or substances that may have been derived from GMO?  yes; GMO per se  the declaration is based on Art. 27 para. 2 TPO  yes, substances that may have been derived from GMO; the form Confirmation regarding substances from GMO HMV4 is enclosed.  n/a, not all components of the medicinal product are known yet |
| Is the medicinal product a radiopharmaceutical?  yes, the *Declaration of radiopharmaceuticals HMV4* form is enclosed.  no |

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| --- |
| Does a draft of the Information for healthcare professionals exist?  yes, the draft of the Information for healthcare professionals is enclosed.  no |
| Does a draft of the Patient information exist?  yes, the draft of the Patient information is enclosed.  no |
| Does an EU SmPC or draft of an EU SmPC exist?  yes, the draft of the EU SmPC is enclosed.  yes, the EU SmPC is enclosed. It was approved on: ……  no |
| Other documents (e.g. other SmPCs from other countries): …… |

# Consents and confirmations

## Confirmation of the recognition of orphan drug status by a foreign authority (according to Art. 4 para. 1 letter adecies no. 2 TPA)

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| The authorisation holder confirms that the foreign medicinal product (or active substance) with orphan drug status is the same medicinal product (same active substance) that forms the subject of this application.  yes  n/a |

# Signature

|  |  |  |  |
| --- | --- | --- | --- |
| **All the entries made in this form are certified to be complete and accurate:**  *(company stamp of the applicant , optional)*  ……  ……  …… | | | |
| *Authorised signatory* | | *Other responsibilities (Optional signature)* | |
| Place, date: ……  Signature: …………………………….. | | Place, date: ……  Signature: …………………………….. | |
| Last name: | …… | Last name: | …… |
| First name: | …… | First name: | …… |
| Position: | …… | Position: | …… |
| Telephone: | …… |  | |
| E-mail | …… |
|  | | | |
| **The application must be sent to** | | **For enquiries contact** | |
| Swissmedic  Swiss Agency for Therapeutic Products  Operational Support Services  Hallerstrasse 7  3012 Bern | | Telephone +41 58 462 02 11  Fax +41 58 462 02 12  E-mail Anfragen@swissmedic.ch | |

Change history

| **Version** | **Change** | **sig** |
| --- | --- | --- |
| 1.5 | New layout, no content adjustments to the previous version. | dei |
| 1.4 | Formal adjustments to the header and footer  No content adjustments to the previous version. | dei |
| 1.3 | Additions/clarifications in chapters 3.2 and 4 | stb |
| 1.2 | Basic information: Deletion of the eCTD sequence no. | dts |
| 1.1 | Addition to chapter 4 “Additional forms and documents to be submitted”:  - Form *Confirmation regarding substances from GMO HMV4*  - Form *Full declaration HMV4* | dts |
| 1.0 | Implementation of TPO4 | dts |